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08/928,272	09/12/1997	MICHAEL J. ISKRA	P-3818	9434
7590 RICHARD J RODRICK BECTON DICKINSON AND COMPANY 1 BECTON DRIVE FRANKLIN LAKES, NJ 074171880			EXAMINER MATTER, KRISTEN CLARETTE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 08/928,272
Filing Date: September 12, 1997
Appellant(s): ISKRA, MICHAEL J.

Kirk M. Miles
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/22/2011 appealing from the Office action mailed 4/26/2011.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner has no comment on the related appeals, interferences, and judicial proceedings contained in the brief.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1 and 5-9 are currently pending and subject to appeal.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

US 5,458,854	BURNS	10-1995
US 4,358,425	FINNEY et al.	11-1982

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior Art (Figures 1-2) in view of Finney et al. (US 4,358,425, herein referred to as "Finney").

Regarding claim 1, Applicant discloses a prior art device in Figures 1-2 that includes a one piece collection container assembly comprising an elongate tubular housing (12) having opposed first and second ends (at 24 and 36), a solid partition contacting a sidewall (12) of the tube forming a closed bottom (26) and positioned within said housing between the first and second ends (see Figures 1-2), said housing defining a volume for specimen collection and containment therein between said first end and said partition (see page 8, line 6), said second end forming a false bottom (32) comprising a bottom end below said partition comprising an annular skirt (28) comprising an opening (36) therein.

The sole difference between the admitted prior art and the instant invention is the bottom of the tube being semi-spherical. However, absent a critical teaching and/or a showing of unexpected results from the tube having a semi-spherical bottom examiner contends that such a modification is an obvious design consideration to one of ordinary skill in the art as a mere change in shape that does not patentably distinguish an invention over the prior art. Changing the bottom to a semi-spherical shape would allow the tube to be compatible with common standard clinical equipment and instrumentation depending on the exact intended use of the tube. In addition, Finney teaches a specimen collection tube with a bottom surface through which fluid is able to pass and having a semi-spherical shape (see Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided

the admitted prior art device with a semi-spherical false bottom as taught by Finney depending on the intended use of the device or to allow compatibility with standard clinical centrifuge equipment (abstract of Finney discusses how such a shape allows the tube to be used in the cavity of a centrifuge rotor) because such a shape was well known at the time of the invention as suitable for such uses. Such a modification would involve substitution of a well known shape (i.e., tube having a semi-spherical bottom) into a well known device to yield predictable results that do not patentably distinguish an invention over the prior art and would have been obvious to try from a finite number of standard centrifuge tube bottom shapes compatible with clinical equipment..

Regarding claim 6, the partition disclosed by the admitted prior art is arcuate in shape (see Figures 1-2).

Regarding claim 9, the admitted prior art is silent as to the dimensions of the container. However, absent a critical teaching and/or showing of unexpected results from making the container the claimed dimensions, examiner contends that it is an obvious design consideration to one of ordinary skill in the art to make the admitted prior art container the claimed dimensions because those dimensions are commonly used for blood/specimen collection containers. In addition, it appears as though the prior art device would perform equally well with the claimed dimensions. See also *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955), in which the court held that mere changes in size do not patentably distinguish an invention over the prior art.

Claims 5, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior Art (Figures 1-2) and Finney, as applied to claims 1, 6, and 9 above, and further in view of Burns (US 5,458,854).

Regarding claim 5, the admitted prior art lacks the partition being arcuate in shape. However, absent a critical teaching and/or a showing of unexpected results from the partition being arcuate (as opposed to conical), examiner contends that such a modification is an obvious design consideration to one of ordinary skill in the art as a mere change in shape without a change in function that does not patentably distinguish an invention over the prior art. In addition, Burns discloses a similar collection container with an arcuate solid partition (38; see Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the shape of the admitted prior art device to be arcuate as taught by Burns in order to effectively separate specimens in the container using a well known method/shape of tube. Furthermore, it appears as though the tube of the admitted prior art would work equally well with any shape of partition so long as specimen could be retained and separated. Such a modification involves the mere substitution of one well known solid partition shape for another to yield predictable results that do not patentably distinguish an invention over the prior art.

Regarding claims 7 and 8, the admitted prior art is silent as to the material of the tube. However, Burns discloses, in a similar collection container, that the tube housing can be made of a thermoplastic polymer such as polyvinyl chloride (column 5, lines 43-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the admitted prior art tube from polyvinyl chloride as taught by Burns in order to use a

well known effective material for storing specimen samples. Such a modification involves the mere use of a well known material in a well known device to yield predictable results that do not patentably distinguish an invention over the prior art. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

(10) Response to Argument

I. Appellant's Admitted Prior Art in view of Finney

Regarding appellant's arguments on page 12 of the Brief that the change in shape is critical, examiner respectfully disagrees. The sole difference between the admitted prior art and the instant invention is the shape of the bottom of the tube, but the change in shape from a flat bottom to a semi-spherical bottom does not patentably change the function of the tube because both shapes previously allowed tubes to be used with standard clinical equipment. Accordingly, changing the shape of the admitted prior art is *not gaining any critical advantage*. In fact, appellant seems to support the conclusion that the shape of the tube bottom is not critical because on pages 13-14 of the Brief appellant acknowledges that both tube shapes were used with standard clinical equipment at the time the invention was made (see for example, first full paragraph on page 13). A mere change in shape without a critical change in function does not patentably distinguish an invention over the prior art.

It is not disputed that both flat bottom and semi-spherical bottomed tubes can be used in various standard clinical equipment as discussed by appellant. However, it is easier to buy a different tube shape than to replace expensive centrifuges, for example, to fit a certain shape of

tube. In addition, the admitted prior art (and instant invention) can be used for blood collection (see background section of the instant specification, for example). The cited Burns reference discloses that blood collection tubes are commonly placed in centrifuges (see column 2, lines 40-50) as is well known in the art. Finney discloses use of the rounded bottom tube in a standard centrifuge (see abstract). As such, those of ordinary skill in the art would recognize the need to place the admitted prior art collection tube in a centrifuge for blood sample analysis and that changing the flat bottom of the admitted prior art tube to a semi-spherical bottom as taught by Finney would allow such a procedure.

In response to appellant's argument that examiner conclusion is based on the specification, examiner respectfully disagrees. Examiner's conclusion is based on mere common sense that different standard clinical equipment, such as centrifuges, may be adapted for a semi-circular tube shape. This is also expressly taught by the Finney reference in the abstract, for example. Appellant cannot claim a monopoly on common sense reasoning just because such a conclusion is acknowledged in the specification.

Regarding appellant's argument that Finney fails to disclose a false bottom, examiner notes that the admitted prior art is what teaches the false bottom. Finney is merely cited to show that a semi-spherical shape with an opening in the bottom was well known and easily manufactured at the time the invention was made. In addition, examiner notes that the plug of Finney can be removed (and likewise must be installed) so the bottom can in fact be considered to be an open or false bottom if need be.

In response to appellant's argument that the examiner's rejections are unsupported, examiner respectfully disagrees and once again points to the fact that motivation was provided in

that the only difference between the admitted prior art and the instant invention is the shape of the bottom, and that the claimed shape of the bottom was well known in the art at the time the invention was made and allowed for compatibility with standard clinical equipment. A mere change in shape from one well known shape to another well known shape without a change in function (i.e., use with various standard equipment is not a critical change in function) does not patentably distinguish an invention over the prior art.

II. Appellant's Admitted Prior Art in view of Finney and Burns

Appellant provides no additional arguments regarding the Burns patent.

(11) Related Proceeding(s) Appendix

Appeal No. 2005-2410 had a decision rendered on September 19, 2005, affirming the examiner.

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided in appellant's Appeal Brief.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Kristen C. Matter/

Primary Examiner, Art Unit 3771

Art Unit: 3771

Conferees:

/Justine R Yu/

Supervisory Patent Examiner, Art Unit 3771

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TC 3700 TQAS